

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON**

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-MD-02327 MDL 2327 JOSEPH R. GOODWIN U.S. DISTRICT JUDGE
THIS DOCUMENT RELATES TO: ETHICON WAVE 4 CASES LISTED IN PLAINTIFFS' EXHIBIT A	

**DEFENDANTS' MEMORANDUM OF LAW IN OPPOSITION TO
PLAINTIFFS' MOTION TO EXCLUDE CERTAIN OPINIONS AND TESTIMONY OF
NICOLE FLEISCHMANN, M.D.**

Defendants Ethicon, Inc. and Johnson & Johnson (collectively, “Ethicon”) respectfully submit this Memorandum in Opposition to Plaintiffs’ Motion to Exclude Certain Opinions and Testimony of Nicole Fleischmann, M.D. (“Dr. Fleischmann”). (Pls.’ Motion [ECF No. 3631]; Exs. A-E [ECF Nos. 3631-1 through 3631-5]; Memorandum [ECF Nos. 3634]).

INTRODUCTION

In seeking to bar certain of Dr. Fleischmann’s opinions and testimony, Plaintiffs mischaracterize both the scope of her opinions and the evidence on which they are based. When Dr. Fleischmann’s opinions are considered within their proper scope, and in light of the broad sources of evidence that inform her opinions—most notably Level 1 peer-reviewed medical literature—her opinions have survived and should still survive Plaintiffs’ latest *Daubert* challenge.¹

¹ Plaintiffs’ motion to exclude Dr. Fleischmann’s opinions on similar grounds in Wave 1 was denied. The Court did exclude some of her opinions, but those rulings do not affect this Motion. *In re: Ethicon Inc. Pelvic Repair Systems Prod. Liab. Litig.*, 2016 WL 4547049 (S.D. W. Va. Aug. 31, 2016).

Nicole Fleischmann is an experienced urologist, pelvic surgeon, Assistant Professor of Obstetrics and Gynecology, and a Fellowship Director who trains fellows in female pelvic medicine and reconstructive surgery. In addition to her extensive training, clinical experience and teaching, she has performed a comprehensive analysis of twenty years of medical literature in authoring her reports. Her opinions are well supported and easily satisfy the *Daubert* challenges raised in Plaintiffs' Motion.

First, Plaintiffs' argument to exclude her opinions regarding mesh pore size ignores this Court's prior rulings and Dr. Fleischmann's qualifications. This Court has already found that Dr. Fleischmann's surgical experience and review of the medical literature allow her to opine on whether the mesh's material properties have any negative clinical impact on patients. Second, for these same reasons, Dr. Fleischmann's opinions regarding the safety and efficacy of Ethicon's mesh products withstand *Daubert* scrutiny. Finally, Dr. Fleischmann's opinions on the adequacy of Ethicon's mesh devices' warnings derive not only from her own extensive use of mesh products, but also from the complications reported in the extensive body of medical literature, and are therefore admissible. Ultimately, Dr. Fleischmann's opinions in each of these areas would be very instructive to the jury and are admissible.

DR. FLEISCHMANN'S PROFESSIONAL BACKGROUND

Dr. Fleischmann is board certified in Urology and Female Pelvic Medicine and Reconstructive Surgery. She is a member of the American Urologic Association ("AUA") and the Society for Urodynamics and Female Urology ("SUFU"). In 1997, she graduated *summa cum laude* from the SUNY Downstate Medical Center where she was a member of the Pathology Honors Society and received the Highest Academic Achievement citation from the American Medical Women's Association. (See Fleischmann 2/8/16 TVT Retropubic MDL General Expert

Report (“Fleischmann TVT Report”), pp. 1-2, Pls. Ex. C, [ECF No. 3631-3]; Nicole Fleischmann, M.D. Curriculum Vitae (“Fleischmann CV”) [ECF No. 2050-3]; Fleischmann 6/6/16 TVT/TVT-O MDL General Expert Report (“Fleischmann TVT/TVT-O Report”), Pls. Ex. D [ECF No. 3631-4]; Fleischmann 1/12/17 Gynemesh PS/Prolift/Prolift+M MDL General Expert Report (“Fleischmann Gynemesh PS/Prolift/Prolift+M Report”), Pls. Ex. B [ECF No. 3631-2]). Dr. Fleischmann completed her general surgical residency in 1999 at the Albert Einstein College of Medicine Montefiore Medical Center, where she stayed to complete her residency in Urology. (*Id.*). In 2004, she completed her fellowship in Female Urology and Voiding Dysfunction at the New York University School of Medicine. (*Id.*). Dr. Fleischmann subsequently served on the faculty at the Mount Sinai School of Medicine as Director of the Female Urology and Voiding Dysfunction. (*Id.*).

Since 2005, Dr. Fleischmann has been a busy clinical practitioner at Westchester Urological Associates, a division of Advanced Urology in White Plains, New York, and an Attending Urologist at the White Plains Hospital Center. (*Id.*). Simultaneously with her private practice, she has also been an Assistant Clinical Professor of Urology and Obstetrics and Gynecology and a Fellowship Director of the Division of Female Pelvic Medicine and Reconstructive Surgery at the Albert Einstein College of Medicine. (*Id.*). In 2011, she was appointed as a Chief of Urology at the White Plains Hospital Center, in which role she continues to serve. (*Id.*).

Dr. Fleischmann’s private practice is almost exclusively dedicated to treating women with various urologic issues, including urinary incontinence and pelvic organ prolapse. (*Id.*). She diagnoses and treats women with stress urinary incontinence on a daily basis. (*Id.*). Once a week, Dr. Fleischmann runs a clinic, didactic sessions and performs surgery at the teaching

hospital. (*Id.*). Two to three days per week, she performs and trains others to perform surgeries to correct stress urinary incontinence. Throughout her career, Dr. Fleischmann has successfully implanted over 1,500 mesh slings, the overwhelming majority of which were TVT products. (*Id.*; Ex. A, Nicole Fleischmann, M.D. 11/24/15 Dep. Tr. (“Fleischmann 11/24/15 Tr.”) at 38:18-24). Dr. Fleischmann has implanted approximately 500 Prolifts and 200 Gynemesh PSs. (Fleischmann Gynemesh PS/Prolift/Prolift+M Report at 62, Pls. Ex. B). She also has treated numerous patients who had an Ethicon pelvic organ prolapse mesh device implanted by another surgeon. (*Id.*).

Based on her education, surgical experience, and extensive examination of the medical literature, Dr. Fleischmann is qualified to as a general expert and Plaintiffs’ Motion should be denied.

LEGAL STANDARD

Ethicon incorporates by reference the standard of review of *Daubert* motions as articulated by the Court in *Edwards v. Ethicon, Inc.*, No. 2:12-cv-09972, 2014 WL 3361923, at *1-3 (S.D. W. Va. July 8, 2014).

ARGUMENT

I. DR. FLEISCHMANN IS QUALIFIED TO OPINE REGARDING WHETHER ETHICON’S MESH’S PORE SIZE HAS ANY CLINICAL IMPACT

Dr. Fleishmann opines that the pore sizes of Ethicon’s mesh are appropriate. (Fleischmann Gynemesh PS/Prolift/Prolift+M Report at 62, Pls. Ex. B; Fleischmann TVT/TVT-O Report at 52, Pls. Ex. D). Her opinion is based her extensive review of the peer-reviewed medical literature and her vast surgical experience. (*Id.*; *see also* Nicole Fleischmann, M.D. 3/15/17 Dep. Tr. (“Fleischmann 3/15/17 Tr.”) at 235:13-236:12, Pls. Ex. E). In similar litigation, under similar circumstances, this Court has found that Dr. Fleischmann is qualified to opine on

the material properties, *i.e.* pore size, of Ethicon's mesh. *In re: Ethicon Inc. Pelvic Repair Systems Prod. Liab. Litig.*, 2016 WL 4547049 at *3 (S.D. W. Va. Aug. 31, 2016). This Court held:

First, the plaintiffs argue Dr. Fleischmann is unqualified to opine on the material properties of polypropylene mesh because she does not have specialized education or training related to the scientific, chemical, or structural composition of mesh, nor does she hold herself out as a materials science expert. This does not, however, necessarily render her unqualified. Dr. Fleischmann is a board-certified urologist with a practice focused on female urology and pelvic floor medicine. She has implanted over 1,500 mesh slings over the course of her career. This extensive clinical experience, combined with her review of peer-reviewed literature, qualifies Dr. Fleischmann to opine on mesh's reaction to and effect on the human body. The plaintiffs' Motion as to qualifications on this matter is DENIED.

Id.

Despite this Court's precedent, Plaintiffs seek to bar Dr. Fleischmann from providing any opinion related to the material property of pore size on the grounds that she is not trained in the field of material science and has no specialized education or research experience regarding scientific, chemical or structural composition of polypropylene and Ethicon's mesh. (Pls.' Memorandum, p. 3). For the reasons set forth below, Dr. Fleischmann's opinions regarding pore size are entirely appropriate and she is qualified to give them.

First, this Court has already found that the same methodology employed by Dr. Fleischmann is sufficiently reliable under *Daubert*. In *Watkins v. Cook, Inc.*, this Court found that a practicing urologist's "comparison of his experience to a reliable and relevant peer-reviewed study ... is enough to open *Daubert's* gates." No. 2:13-cv-20370, 2015 WL 1395773, at *13 (S.D. W. Va. March 25, 2015). In *Tyree v. Boston Scientific Corp.*, this Court concluded that a urologist's clinical experience and review of the scientific literature, which he explained and cited throughout his report, "are sufficiently reliable bases" to opine that he has not seen

“evidence of polypropylene degradation, systemic infection, or other unexpected reactions.” 54 F. Supp. 3d 501, 585 (S.D. W. Va. 2014). “[T]he rejection of expert testimony is the exception rather than the rule.” F.R.E. 702, advisory committee’s notes – 2000 amendment; *see also Whitfield v. Southern Maryland Hosp., Inc.*, DKC 12-2749, 2014 WL 923255, at *9 (D. Md. March 7, 2014). If Plaintiffs so choose, they can test the soundness of Dr. Fleischmann’s conclusions on cross-examination at trial, or challenge her for not being a polymer chemist. *See id.* At this juncture, however, her thorough review of the medical literature regarding the clinical impact of the material properties of mesh, combined with her extensive surgical experience, render her opinions admissible at trial.

Plaintiffs also argue that Dr. Fleischmann should not be allowed to testify regarding pore size because of an alleged “lack of familiarity with literature discussing pore size significance” and alleged “speculative” testimony regarding whether pore size could change under tension. (Pls.’ Memorandum, p. 3). At bottom, these misconstrued and distorted sound bites are, at best, fodder for cross-examination. *See In re Ethicon, Inc.*, 2016 WL 4547049 *3 (“The plaintiffs’ concerns about Dr. Fleischmann’s literature review are better suited for cross-examination.”).

As this Court has held, examining the same qualifications presented in the present case, Dr. Fleischmann is qualified to testify regarding the clinical significance of the pore size of Ethicon’s mesh devices and has used reliable methodology rooted in her examination of the vast body of the medical literature to arrive at her opinions.

II. DR. FLEISCHMANN IS QUALIFIED TO TESTIFY ABOUT THE SAFETY AND EFFICACY OF ETHICON’S MESH PRODUCTS.

Plaintiffs also seek to preclude Dr. Fleischmann from offering opinions on whether Ethicon’s mesh devices “are not defectively designed,” because she has no training or expertise

in “mesh product design.” (Pls. Memorandum pp.4-5). Plaintiffs’ Motion on this point should be rejected for substantially the same reasons outlined in Point I.

Dr. Fleischmann’s qualifications and methodology pass *Daubert* scrutiny. As noted above and consistently held by this Court, the fact that Dr. Fleischmann is not an engineer or materials scientist does not affect her competency to opine upon the safety, efficacy, and clinical significance of Ethicon’s mesh products. The Court has consistently found similar challenges to be “without merit” and noted that Ethicon’s urogynecologist experts’ “extensive clinical and research experience qualifies [them] to opine on mesh’s reaction to and effect on the human body, and relatedly, the safety and efficacy of mesh products.” *In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, 2016 WL 45493666, at *3 (S.D. W. Va. Aug. 25, 2016); *In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, 2016 WL 4556807, at *4 (S.D. W. Va. Aug. 31, 2016).

Whether Dr. Fleischmann should be barred from using the term “not defectively designed” when speaking to safety and efficacy should be decided by the trial judge upon remand who can carefully craft an instruction after weighing any alleged prejudicial impact of this specific testimony. *In re: Ethicon, Inc.*, 2016 WL 4547049 at *3.

III. THIS COURT HAS INSTRUCTED THAT EXPERTS, SUCH AS DR. FLEISCHMANN, ARE QUALIFIED TO TESTIFY ABOUT THE SPECIFIC RISKS OF THE MESH DEVICES AND WHETHER THOSE WARNINGS APPEARED IN THE IFU.

Plaintiffs also seek to preclude Dr. Fleischmann from offering opinions on the adequacy of Ethicon’s product warnings because this Court has previously held that “Dr. Fleischmann does not possess the additional expertise to offer expert testimony about what an IFU should or should not include.” *In re: Ethicon, Inc.*, 2016 WL 4547049 *3 (S.D. W. Va. Aug. 31, 2016).

Ethicon does not seek to re-litigate this issue, but Ethicon notes that Plaintiffs’ Memorandum blatantly ignores this Court’s guidance that: “While an expert who is a urologist

may testify about the specific risks of implanting mesh and whether those risks appeared on the relevant IFU, the same expert must possess additional expertise to offer expert testimony about what information should or should not be included in an IFU.” *Id.* (emphasis added). Therefore, Dr. Fleischmann should not be barred from testifying on the specific risks of the Ethicon mesh procedures and whether those risks appeared in the IFU.

Finally, this Court has consistently instructed that its prior rulings regarding impermissible IFU testimony do not pertain to whether that expert can testify whether certain risks were commonly known in the medical community. *See, e.g., In re: Ethicon, Inc.*, 2016 WL 4582231 *3 n.2 (S.D. W. Va. Sept. 1, 2016); *In re: Ethicon, Inc.*, 2016 WL 4536875 *4 n.2 (S.D. W. Va. Aug. 30, 2016); *In re: Ethicon, Inc.*, 2016 WL 4493364 *4 n.2 (S.D. W. Va. Aug. 25, 2016). Here, Plaintiffs have not moved to exclude any of Dr. Fleischmann’s opinions regarding what constitutes “risks [] commonly known in the medical community.” Dr. Fleischmann is clearly qualified to offer such opinions based on her extensive experience and review of medical literature.

CONCLUSION

For these reasons, Plaintiffs' Motion to Exclude Certain Opinions and Testimony of Ethicon's Expert Dr. Fleischmann should be DENIED.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on April 27, 2017, I electronically filed this document with the clerk of the court using the CM/ECF system, which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

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